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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,297	03/01/2005	Takeshi Matsuda	10921.0288USWO	6278

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EXAMINER
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WHITE, DENNIS MICHAEL

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/526,297	<b>Applicant(s)</b> MATSUDA ET AL.	
	<b>Examiner</b> DENNIS M. WHITE	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2005 is/are: a) ☒ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/01/2005, 11/24/2006</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION*****Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “penetration membrane has a honeycomb structure” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. "Honeycomb structure" is unclear as to the metes and bounds of the claim since no explanation in the claim or specification is provided as to what structure the honeycomb is referring to. Is the honeycomb the exterior design of the membrane? Is the honeycomb referring to how the interior pores are aligned?

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-7, 9-10, 13, 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Gibson et al (USP 5,527,509).

Regarding claims 1 and 4-7, Gibson et al teach a colorimetric enzymatic analytical test element ("test kit") comprising a plurality of reaction zones incorporating a dried enzyme composition, dyestuff, and reagent for colorimetric

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analysis ("penetration layer"), and a Cyclopore membrane ("pores have a size of 0.1-12  $\mu\text{m}$ " "porosity of 4-20 vol %" "formed by track etching") overlies the zone ("a plurality of coloration pads held in contact with the penetration layer" "a penetration membrane which are formed with a plurality of thicknesswise extending pores"), wherein a liquid sample is applied to the membrane and allowed to penetrate to the zone ("supplied to the penetration layer is fed to each of the coloration pads through the penetration layer, and wherein the penetration layer allows liquid penetration mainly thicknesswise of said penetration layer while restricting liquid penetration in a planar direction of the penetration layer") (Figure 10: 15 and 16, col. 8 lines 7-23).

Regarding claim 2, Gibson et al teach the reaction zones ("the plurality of coloration pads") and the membranes ("penetration layer") are laminated in this order on a carrier (Figure 7 and 10).

Regarding claim 3, Gibson et al teach the filter ("the penetration layer") and the enzyme containing discs ("plurality of coloration pads") are laminated in this order on an absorbent ("water absorbent carrier") (Figure 7 and 8: 5, 8 and 9, col. 7 lines 47-col. 8 line 7).

Regarding claim 9, Gibson et al teach the reaction zones are disposed in spaced relation along the strip ("wherein the plurality of coloration pads are arranged in a matrix") (Figure 9:16, col. 2 lines 28-30).

Regarding claim 10, Gibson et al teach the selection of appropriate dyestuffs may allow different colours to be displayed ("at least two of the plurality

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of coloration pads differ from each other with respect to coloration components for allowing measurement of a plurality of items”) (col. 2 lines 31-34).

Regarding claim 13, Gibson et al teach a method for producing a test kit, comprising: printing reagents to the support which incorporate a dried enzyme composition and dyestuff (“a first step of forming a plurality of coloration pads by coating a carrier with a reagent liquid containing a coloration component using a non-contact dispenser and by thereafter drying the reagent liquid”); and a applying a membrane to the reaction zone (“second step of intimately attaching a penetration membrane so as to cover the plurality of coloration pads”), wherein the sample liquid is applied to the membrane and allowed to penetrate to the reaction zone (“penetration membrane used in the second step allows liquid penetration mainly thicknesswise of said penetration membrane while restricting liquid penetration in a planar direction of the penetration membrane”) (col. 8 lines 7-23).

Regarding claim 15, Gibson et al teach the reaction zones are disposed in spaced relation along the strip (“wherein the plurality of coloration pads are formed in a matrix arrangement in the first step”) (Figure 9:16, col. 2 lines 28-30).

Regarding claim 16, Gibson et al teach the selection of appropriate dyestuffs may allow different colours to be displayed (“wherein, in the first step, at least two of the plurality of coloration pads differ from each other with respect to coloration components”) (col. 2 lines 31-34).

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***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gibson et al (USP 5,527,509) and in view of McAleer et al (USP 5,951,836).

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Gibson et al teach the limitations of claims 1 and 4 as per above.

Gibson et al teach the membrane ("penetration membrane") is selected from a group consisting of Nucleopore, Isopore, Cyclopore, Nylon, PTFE, Polyester or other suitable membrane and the device is used for glucose detection. Gibson et al is silent about the membrane having a honeycomb structure.

McAleer et al teach a disposable glucose test strip which comprises a two-dimensional network which takes the form of a honeycomb which excludes red blood cells. It is advantageous to provide a membrane to exclude red blood cells in a glucose test substantially insensitive to the hematocrit of the sample (col. 4 lines 38-55).

Therefore it would have been obvious to one of ordinary skill in the art to provide the membrane of Gibson et al with the honeycomb structure of McAleer because in order to exclude red blood cells and make the test insensitive to hematocrit.

10. Claims 11-12 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibson et al (USP 5,527,509) and in view of Iwata et al (US 2001/0028862)

Gibson teaches the limitations of claims 1 and 13 as per above.

Regarding claims 11-12 and 17-18, Gibson et al teach apparatus and method of producing the device comprising the discs or reaction zone paper of 5 mm can be cut from the dried papers and mounted on the paper or card (col. 6 line 33). Gibson et al are silent about reaction zones or region ("the plurality of



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coloration pads”) are formed within a specific region, and the surface area of the specific region is 2.0-15 mm x 2.0-15 mm and wherein the surface area of the specific region accounted for by the respective coloration pads is no more than 2.0 mm<sup>2</sup>.

Iwata et al teach a test device and method of producing the device for a multi-items where in all the test papers for all items for one test are wetted by one shot dropping and transportation of a detecting part or a test device is not required upon measurement. The reaction zone for the horizontal line is preferably 8mm to 2cm and the vertical line is preferably 4 to 10mm. The diameter of the micro test papers (“coloration pads”) is being 0.5 mm (“wherein the surface area of the specific region accounted for by the respective coloration pads is no more than 2.0 mm<sup>2</sup>”) (Para. 0082 and 0084). It would have been desirable to have the dimensions of the total surface area of the reaction zone and the micro test papers (“coloration pads”) within this range because having the micro test papers size too large, it becomes difficult to wet the test papers for the whole items by one shot dropping of the sample (Para. 0084).

Therefore it would have been obvious to one of ordinary skill in the art to provide Gibson et al device with the dimension of the surface area of the region of the reaction zones or region (“the plurality of coloration pads”) within 2.0-15 mm x 2.0-15 mm and wherein the surface area of the specific region accounted for by the respective coloration pads is no more than 2.0 mm<sup>2</sup> because it provides the above advantages of one shot dropping of the sample.

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11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gibson et al (USP 5,527,509) and further in view of Goerlach-Graw et al (USP 5,424,220)

Gibson teaches the limitations of claim 13 as per above.

Regarding claim 14, Gibson et al teach the reagents are applied to the support by printing, for example screen printing and mask printing. Gibson et al are silent about the non-contact dispenser used in the first step is of an inkjet type.

Goerlach-Graw et al teach a analysis element comprising a chromatographic porous carrier, reaction zone, detection zone, and absorptive zones. The reagents can be applied with screen printing or ink-jet printing. It is desirable to use an ink-jet printing because it allows the application of smaller portions of reagent liquid.

Therefore it would have been obvious to one of ordinary skill in the art as motivated by Goerlach-Graw et al to use an ink-jet printer to print the reagents of Gibson et al in order allow the application of smaller portions of reagent liquid.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571)270-3747. The examiner can normally be reached on Monday-Thursday, EST 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

dmw

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797